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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/186,342	11/04/1998	DARRELL C. CONKLIN	97-64	1674

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EXAMINER	
LAZAR WESLEY, ELIANE M	
ART UNIT	PAPER NUMBER
1646	14

DATE MAILED: 12/13/2001

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.	Applicant(s)
09/186,342	Conklin
Examiner	**Art Unit**
Eliane Lazar-Wesley	1646

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1) ☒ Responsive to communication(s) filed on *Aug 7, 2001* .

2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.

3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

4) ☒ Claim(s) *2, 3, 5, 10-14, 16-22, and 24* is/are pending in the application.

4a) Of the above, claim(s) *11-14 and 16-21* is/are withdrawn from consideration.

5) ☐ Claim(s) _____ is/are allowed.

6) ☒ Claim(s) *2, 3, 5, 10, 22, and 24* is/are rejected.

7) ☐ Claim(s) _____ is/are objected to.

8) ☐ Claims _____ are subject to restriction and/or election requirement.

Application Papers

9) ☐ The specification is objected to by the Examiner.

10) ☐ The drawing(s) filed on _____ is/are objected to by the Examiner.

11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved.

12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

13) ☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

a) ☐ All b) ☐ Some* c) ☐ None of:

1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____ .
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

*See the attached detailed Office action for a list of the certified copies not received.

14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

15) ☐ Notice of References Cited (PTO-892)

16) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)

17) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s). _____

18) ☒ Interview Summary (PTO-413) Paper No(s). 14

19) ☐ Notice of Informal Patent Application (PTO-152)

20) ☐ Other:

DETAILED ACTION

1. The amendment after final filed August 07, 2001, has been entered.

Claims 2, 3, 5, ~~10~~ 26, 22 and 24 are under consideration.

Prosecution is reopened. The allowability of claim 10 is withdrawn.

Claim Rejections - 35 USC § 101 /112, first paragraph

2. 35 U.S.C. 101 reads as follows:

> Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

3. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

4. Claims 2, 3, 5, 22 and 24 remain or are rejected under 35 U.S.C. 101 for the reasons of record in the former office action, because the claimed invention is not supported by either a specific asserted utility or a well established utility.

The nucleic acid encoding z219c has been obtained by scanning of translated database and confirmation of EST sequence (page 84, example 1).

The specification sets forth various utilities for the claimed nucleic acid and encoded protein; however, none are specific to the nucleic acid claimed. Applicants disclose that, by performing Northern blot analysis, (Example 2, page 85 and page 86), the nucleic acid shows a wide tissue distribution for z219c (trachea, stomach,colon, pancreas, prostate, small intestine, salivary gland, kidney, fetal kidney, fetal liver, fetal spleen, fetal thymus, and fetal lung). Applicants also show a chromosome localization for z219c (Example 3). While applicants recite that z219c expression has been detected by Northern analysis at various levels in numerous tissues, applicants do not teach where z219c is not expressed. The fact that z219c is expressed in some selected tissues does not exclude *per se* thatz219c is not expressed also in other tissues. One of skill in the art must know where the nucleic acid is not expressed in order for it to be useful , for example in tissue identification.

The assertions of utility are found to be non-specific, as they could apply equally to any nucleic acid or encoded protein obtained from nature, and thus do not fulfill the requirements of 35 U.S.C. 101.

Applicants argue that the polynucleotides of the invention constitute probes that have a diagnostic utility due to their chromosomal localization at 3q21.1-p13.

Applicant's arguments have been considered but have not been found persuasive for the following reasons: the chromosomal localization claimed for the polynucleotide of the invention spans over a quite large fragment of chromosome 3 (3p21.1-p13 region of chromosome 3), and no

specific localization is provided allowing determination of where the probe actually hybridizes, and if the site of hybridization corresponds to a marker for a specific disease characterized, for example, by a specific deletion or mutation. It is well known in the art that, for chromosomal markers to be specific, they have to map to a specific site, which is supported by the fact that researchers usually need a set of closely spaced markers to assess for example an interstitial break (see for example Shridhar, Oncogene, 14: 1269-77, 1997 at page 1271, col.2). Applicants recite that ARP maps to 3p21.1, and that deletions in ARP are associated with solid tumors of various types, and deletions and mutations at codon 50 are observed in pancreatic tumors. However, there is no evidence that the polynucleotide of the invention maps to the site of ARP, and has any link to ARP. There is no evidence that LOH (loss of heterozygosity) is associated with the polynucleotide of the invention. The argument that a chromosomal deletion of the fragment hybridizing to the probe would provide a specific and well established utility is not persuasive because, although chromosomal deletions or translocations are known to be associated with various tumors (see for example Cigurosa, Genes, chromosomes and cancer 25:123-133, 1999, at page127, col.2), there is no nexus between the claimed nucleic acid and any known deletion, nor sufficient information to allow the use of the claimed nucleic acid for the detection of any deletion or other alteration associated with any known tumor or other condition.

In the response of October 30, 2001, Applicants argue that there are markers in the 3p21.1-p13 regions which are diagnostic of cancer and malignancies. However, there is no evidence that absence or abnormalities of this specific gene are predictive of cancer or of any other disease.

Applicants provide references supporting an asserted utility to diagnose cancer by detecting abnormalities in this region. However, the specification also teaches that markers in the same region serve to diagnose for example neurosensory nonsundromic recessive deafness (at 3p21-p14), Larsen syndrome (at 3p21.1-p14.1), and non-ketotic type II hyperglycinemia (at 3p21.2-p21.1).

The instant gene z19c is only mapped to the general region and its own specific association with a disease is not established. Therefore, it may be used to detect general chromosomal abnormalities only, which is not a specific utility since any nucleotide sequence may be used to do that.

5. Claims 2, 3, 5, 22 and 24 remain or are also rejected under 35 U.S.C. 112, first paragraph. Specifically, since the claimed invention is not supported by either a specific asserted utility or a well established utility for the reasons set forth above, one skilled in the art clearly would not know how to use the claimed invention.

Claim Rejections - 35 USC § 112

6. Claim 10 is rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Claim 10, as amended in the communication filed on October 30, 2001, recited a sequence of amino acid residues 1(Met) through **25 (Gly)** of SEQ ID No:2. However, the specification and the

original claim 10 recite amino acid residues 1(Met) through 21(Gly) of SEQ ID No:2, and there is no support for amino acid residues 1(Met) through 25 (Gly) of SEQ ID No:2.

While applicants state, page 5 of the response, that the claim 10 of the response is properly stated without error, the instant response does not provide a corrected version of the claim. Claim 10 stands as in the amendment of October 30, 2001, and therefore presents new matter.

7. No claim is allowed.

8. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

9. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Eliane Lazar-Wesley, PhD, whose telephone number is (703) 305 4059. The examiner can normally be reached on Monday-Friday from 9:30am to 5pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Yvonne Eyler, can be reached on (703) 308-6564.

Official papers filed by fax should be directed to (703) 308 4242. Faxed draft or informal communications with the examiner should be directed to (703) 308-0294.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-0196.

ELW
December 05, 2001
ELW

LORRAINE SPECTOR
PRIMARY EXAMINER